

QINGDAO HAINUO GROUP

About us

Hainuo Group was founded in 2004 and now has more than 20 subsidiary corporations. Our headquarter is located in Jiangshan industrial park in Laixi, Qingdao, which is very close to the main highway, Qingdao International Airport and Qingdao Harbor. Our factory covers an area of 220,000 square meters with super geographical position and convenient transportation.

We have a dozen up-to-date factories, multiple Class 100,000 cleanrooms and Class 300,000 cleanrooms, modern logistics and storage facilities, advanced production facilities and detecting instruments. More than 2,000 professional staffs devote themselves to their job and the development of Hainuo. We also have technology support and cooperation of many research institutions and companies from USA, Germany and Taiwan, China.

Hainuo keeps moving forward and we're always open to your ideas and advices. Please don't hesitate to let us know if you're interested in working with us and a deeper level of cooperation!

OUR BRANDS



HYNAUT for Overseas Market



HAINUO for Domestic Market



3强实企
STRONG FIRM
品牌质量加持

HAINUO

HAINUO

HAINUO 青岛海氏海诺集团

Ethyl Alcohol Prep Pad



Your Professional Partner
of Medical Care



Ethyl Alcohol Prep Pad

Hynaut Ethyl Alcohol Prep Pad is made of spunlace non-woven fabric, saturated with 75% ($\pm 5\%$) ethyl alcohol.

FEATURES:

△ Topical antiseptic helps to reduce bacteria on the skin and makes these pads ideal for use prior to injections.

△ Ideal for removal of oils and residue from skin.

△ Each pad is individually wrapped and sealed to keep it protected and moist.



Specification	Carton Size	Packaging	GW
6*3cm	46.5*35*33.5cm	100pcs/box*100boxes=10000pcs	9.78kgs
6*6cm	58*38.5*33cm	100pcs/box*100boxes=10000pcs	14.61kgs
12*12cm	58*32*31cm	50pcs/box*60boxes=3000pcs	12.8kgs

Ethyl Alcohol Prep Pad



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Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 result found for Establishment Registration
or FEI Number : 3008808560

New Search

Establishment Name	Registration Number	Current Registration Yr
QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD. CHINA	3008808560	2020
<ul style="list-style-type: none"> Floss, Dental - Floss Pick First Aid Kit Without Drug - First Aid Kit Pad, Alcohol, Device Disinfectant - Alcohol Wipes, Alcohol Prep Pad Dressing, Wound, Hydrophilic - Wound Dressing I.V. Adhesive Dressing Tape And Bandage, Adhesive - Medical Tape, Adhesive Bandage, Wound Plaster Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Iie Guidance Mask, Scavenging - Disposable Mask Disinfectant, Medical Devices - Iodine Swab Pack, Hot Or Cold, Disposable - Warm Patch, Cold Pack, Cool Patch, Fever Relief Patch, Cool Gel, Freeze Gel Bandage, Elastic - Elastic Bandage, Gauze Bandage Non-Surgical Isolation Gown Gauze / Sponge, Nonresorbable For External Use - Gauze Pad, Underpad, Cotton Balls Cover, Shoe, Operating-Room Mouthguard, Over-The-Counter - Face Mask Applicator, Absorbent Tipped, Non-Sterile - Cotton Swab Cap, Surgical 		Manufacturer

FDA

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Hynaut Alcohol Prep Pad	78149-002-01	70 mL/100g	CLOTH	TOPICAL	part333A	Qingdao Hainuo Biological Engineering Co., Ltd.	78149-002	Alcohol	ALCOHOL	HUMAN OTC DRUG	06/23/2020	N/A	OTC MONOGRAPH NOT FINAL	1 PATCH in 1 PACKAGE (78149-002-01) > 2.7 g in 1 PATCH
Alcohol Prep Pads	78149-201-02	75 gr/100g	SWAB	EXTRACORPOREAL; TOPICAL	part333A	Qingdao Hainuo Biological Engineering Co., Ltd.	78149-201	Alcohol Prep Pads	ISOPROPYL ALCOHOL	HUMAN OTC DRUG	05/20/2020	N/A	OTC MONOGRAPH NOT FINAL	100 PATCH in 1 BOX (78149-201-02) > 7 g in 1 PATCH (78149-201-01)
Alcohol Prep Pads	78149-201-04	75 gr/100g	SWAB	EXTRACORPOREAL; TOPICAL	part333A	Qingdao Hainuo Biological Engineering Co., Ltd.	78149-201	Alcohol Prep Pads	ISOPROPYL ALCOHOL	HUMAN OTC DRUG	05/20/2020	N/A	OTC MONOGRAPH NOT FINAL	100 PATCH in 1 BOX (78149-201-04) > 1.05 g in 1 PATCH (78149-201-03)

NDC

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2020-09-03

To Whom It May Concern

This is to confirm that Extension Audit, Re-certification Audit for ISO 13485, Surveillance Audit for MDD was carried out on behalf of TÜV Rheinland LGA Products GmbH Notified Body (CE0197) as follows:

Applicant: **Qingdao Hainuo Biological Engineering Co., Ltd.**
Address: **Jiangshan Industrial Area of Jiangshan Town, Laixi, 266603
Qingdao City, Shandong, China**

MDDScope: **Aspects of manufacture concerned with securing and maintaining sterile conditions of Sterile Wound Plasters, Sterile Wound Dressings, Medical Face Masks**

qsScope: **Manufacture and Distribution of Sterile Wound Plasters, Sterile Wound Dressings, Medical Adhesive Tapes, Surgical Sponges, Medical Cotton Tipped Applicators, Medical Cotton Balls, Medical Alcohol Prep Pads, Medical Alcohol Cotton Balls, Medical Iodine Cotton Balls, Medical Face Masks, Medical I.V. Adhesive Dressings, Human Chorionic Gonadotropin(HCG)Test Strips (colloidal gold), Luteinizing Hormone (LH)Test Strips (colloidal gold), Medical Fever Relief Patches, Gauze Bandages, Elastic Bandages, Medical Underpads, Medical Instant Cold Packs, Medical Exam Gloves, Liquid Dressings**

Standards: **EN ISO 13485:2016, MDD 93/42/EEC Annex V**

Date: 2020-06-22~24
Report No.: 15081837 011

The result of on-site audit is positive. The auditors will recommend that TÜV Rheinland LGA Products GmbH Notified Body (CE0197) Certificate for a Quality Assurance System should be issued after the corrective actions proposed by the company are accepted.

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

Mr. SHENG Fuxiu
Leader Auditor, Greater China
Medical Services

TÜV Rheinland
(Shanghai) Co., Ltd.

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ISO 13485

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中华人民共和国医疗器械注册证

注册证编号：鲁械注准 20172640675

注册人名称	青岛海诺生物工程有限公司
注册人住所	青岛市莱西市姜山镇工业园
生产地址	青岛市莱西市姜山镇工业园
代理人名称	（“进口医疗器械适用”）
代理人住所	（“进口医疗器械适用”）
产品名称	医用酒精消毒棉片
型号、规格	3cm×3cm、4.5cm×9cm、5cm×5cm、6cm×3cm、6cm×6cm、8cm×8cm、6cm×12cm、10cm×10cm、10cm×15cm、10cm×20cm、12cm×12cm、12cm×18cm、12.5cm×16cm、13cm×16cm。
结构及组成	由水刺无纺布片浸浓度为70%—80%（体积分数）的医用酒精制成。
适用范围	用于注射、输液前消毒完整皮肤。
附件	注册产品技术要求：鲁械注准 20172640675
其他内容	
备注	

审批部门：山东省食品药品监督管理局



批准日期：2017年09月04日
有效期至：2022年09月03日



Business License


Medical Device Registration

Ethyl Alcohol Prep Pad



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 SDS No. 20200428251

*Experts on International Rules&Regulations for Training, Packing, Storage&Transport of Hazardous Goods
Dangerous Goods Management(China) Ltd.*

Material Safety Data Sheet

Product name: **AlcoholPrep Pad**

Manufacturer or Supplier: **Qingdao Hainuo Biological Engineering Co., Ltd.**

MSDS prepared by DGM China
Web: www.dgmchina.com.cn

Safety Data Sheet

AlcoholPrep Pad

Version: V1.0.0.1
SDS No. 20200428251
Creation Date: 2020/04/28
Revision Date: 2020/04/28

*Prepared according to UN GHS (the 8th revised edition)

1 Identification of the chemical and supplier

Product identifier

Product Name	AlcoholPrep Pad
Product Model	6*3cm
CAS No.	Not applicable
EC No.	Not applicable
Molecular Formula	Not applicable

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Topical skin disinfection.
Uses advised against	No special note.

Details of the supplier of the Safety Data Sheet

Name of the company	Qingdao Hainuo Biological Engineering Co., Ltd.
Address of the company	Jiangshan Industrial Area of Jiangshan Town, Laixi, Qingdao, Shandong, 266603, China
Post code	266603
Telephone number	+86 532-86464444
Fax number	+86 532-86464444
E-mail address	Lizi1002@126.com

Emergency phone number

Emergency phone number	+86 532-86464444
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2 Hazards identification

Hazard classification according to GHS

Hazard classification according to GHS	Not applicable
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Label elements

Hazard pictograms	Not applicable
Signal word	Not applicable

Hazard statements

Hazard statements	Not applicable
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Precautionary statements

Material Safety Data Sheet (MSDS)

Ethyl Alcohol Prep Pad



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空运
By Air

NO.2020067152

CNAS 中国认可
检验 INSPECTION
CNAS B0071

货物运输条件鉴定书

Certification
for Safe Transport of Chemical Goods

非限制性货物

样品名称：酒精棉片（单片包装）
Sample Name: alcohol prep pad

委托单位：青岛海诺生物工程有限公司
生产单位：青岛海诺生物工程有限公司

上海化工院检测有限公司
Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空运
By Air

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2020067152

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样品名称 Sample Name	中文 Chinese	酒精棉片（单片包装）
	英文 English	alcohol prep pad
委托单位 Consignor	青岛海诺生物工程有限公司	
生产单位 Manufacturer	青岛海诺生物工程有限公司	
检验方法、程序 Inspection Methods and Procedures	国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition	
样品外观与气味 Appearance & Odor	白色湿无纺布，稍有气味 White Wet nonwoven, Weak odor	
鉴定 结论	1. 危险性识别 (Hazards identification)	无。 None.
	2. 空运按照IATA DGR办理的类别 (Suggestion according to IATA DGR)	根据特殊规定A46，可按非限制性货物条件办理。 The substance is not subject to IATA DGR according to special provision A46.
	3. 包装要求 (Packaging requirements)	无。 None.
备注 Comment	无。 None.	

批准 Approver: 张小明 审核 Checker: 董宇彤 主检 Appraiser: 周敏



Certification for Safe Transport of Chemical Goods



Contact us!



QINGDAO HAINUO GROUP

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Province, China*

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